

## Remarks

### **1. Summary of Office Action**

Claims 1-18 are pending. Claims 3 and 11 have been canceled herein.

Claims 1, 10 and 16 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner rejected the above-noted claims because "the step of using milk surge data to subsequently effect one or more of a subsequent therapeutic, diagnostic or modified milk expression technique is not present in the specification as originally filed," and not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, has possession of the claimed invention.

Claims 1, 2, 6-7 and 9-18 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Alekseev et al. (*Compression stimuli increase the efficacy of breast pump function*. European Journal of Obstetrics & Gynecology). Claims 3, 4, 5 and 8 were rejected as being obvious under 35 U.S.C. 103(a) in view of Alekseev et al. in combination with Jaquith (U.S. 4,030,356).

### **2. Response to Rejections**

The Examiner alleged that the step of using milk surge data to subsequently effect one or more of a subsequent therapeutic, diagnostic or modified milk expression technique is not present in the specification as originally filed. However, these aspects of the invention are shown and discussed in several places in the specification as originally filed. Also, reference is made in the pending application to WO 01/47577, which is owned by the Assignee of record of the present case, and which also provides support for the claim language and scope.

The Abstract of this invention, for example, states, "Application areas are research, in order

to gain new knowledge about the breast-feeding behavior of babies and mothers, hospitals and child welfare clinics, in order to resolve breastfeeding problems, and development departments, for the purpose of optimizing breast pumps." So it is clear that the present application contemplates use of surge data as recited in the claims for therapeutic and diagnostic purposes ("resolve breastfeeding problems," and for optimizing pumping ("modified milk expression").

A specific example is furthermore provided of diagnostic and therapeutic applications of surge data on page 6 of the application and beginning on line 25, reproduced hereinbelow:

The milk collected in the several containers 2', 2", 2" can be analyzed and also used individually. For example, as milk is removed from the breast the fat content of the milk increases and this system allows to track that increase.

This technique is extremely beneficial for mothers of premature infants for whom the energy density of milk is very important. The fat is responsible for approximately 50% of the energy in milk therefore, collecting the milk in fractions will provide volumes of milk with different energy densities. These can then be used individually or certain fractions can even be mixed to provide milk of specific energy density—an energy density best suited to the infant's needs.

From the above, it is clear that the present invention sets out a technique to use the present system to analyze the milk of and diagnose conditions related to fat content of milk over time; and design therapeutic treatment of infants to provide milk of specific energy density. Here again, diagnosis and therapeutic treatment are aspects of the invention present in the specification as originally filed.

As an example of optimizing breast pumps, and specifically, milk expression technique, the present application, in the Background of the Invention, states that, "...essential information for...optimizing breast pumps may be derived from the mother's milk surge." In the Summary of the Invention, the application notes that, "The quantity of milk is preferably directly determined or calculated. This allows the point in time and also the intensity of the milk surge to be detected to better effect." In the next paragraph of the Summary, "The measurement results and measurement curves obtained in this way can be evaluated..." and "The results may also be used in product development, for the purpose of optimizing breast pumps."

So, the specification as filed shows how the inventors considered how milk surge information can be obtained and used to optimize breast pumps for modified milk expression, as well as for therapeutic and diagnostic purposes. Furthermore, the application states that the pump set out in WO 01/47577, "imitates the suckling rhythm of a baby and allows milk to be expressed from the breast in as natural a manner as possible." Since the pumps of WO 01/47577 are programmable, it can be seen that with the accurate surge data obtained with the present invention, the pumps of WO 01/47577 can be programmed to produce operation with modified milk expression technique, as for example, to imitate the change in the suckling rhythm of a baby at a time when the baby naturally changes from a letdown rhythm to an expression rhythm.

Since the application includes teaching directed to use of the claimed apparatus with the results useful in therapeutic, diagnostic or modified milk expression techniques, the rejection under 35 C.F.R. § 112, first paragraph, should be withdrawn.

Amended Claim 1 is substantially a combination of former Claim 1 (as filed on December 18, 2007) and features of Claims 3 and features discloses on page 5, last paragraph of the description of originally filed. Claims 2, 4 and 8 are amended accordingly. Claim 3 is canceled. Independent

Claims 10 and 16 are amended in accordance with Claim 1 and Claim 11 as well.

In the system according to new Claim 1, a balance is used to weigh the milk expressed during expression. Accordingly, the method according to new Claims 10 and the use according to new Claim 16 weigh the milk.

Alekseev et al. disclose a system for detecting a milk surge, where this system is shown in figure 1 on page 133. A breast shield 3 is arranged on a mother's breast. The breast shield is connected with a milk bottle 6. The milk bottle 6 is arranged in a holder 7 which is stiffly connected to the solid body 2, which is arranged around the breast shield 3. The bottle 6 is graduated at 1 ml. intervals in order to determine the rate of milk removal.

Alekseev et al. do not therefore disclose a balance, which the Examiner acknowledges. Alekseev et al. also does not disclose a connecting tube enabling the mother to move around during expression (without affecting the accurate detection of surge data). Therefore, the subject matter of Claims 1, 2, 6-7 and 9-18 are not anticipated by Alekseev et al.

Alekseev et al. disclose a bottle with a graduation of 1 ml. intervals. The bottle is held in the holder 7, which is stiffly connected to the solid body 2, which is pressed against the mother's breast. This corresponds to the known milk expression assemblies for expressing mother's milk. As for example shown in WO 01/47577, the milk collection bottle is normally attached to the breast shield and it is held by the mother during milk expression.

Jaquith discloses a continuous weighing mechanism for fluids. Just using this balance in the arrangement of Alekseev et al. would not end in a working system. Therefore, the combination of Alekseev et al. and Jacquith is not logical, and does not lead to the claimed invention. Since the milk bottle is stiffly connected with the solid body 2, and this solid body 2 is pressed against the mother's breast, the balance would not weigh the milk but the whole system, including the breast shield and

the holder 2 as well as parts of the mother. Every movement of the mother would change the measured data. Furthermore, the balance would have to be supported as well, since it cannot be laid on the table, without forcing the mother into an uncomfortable position. Since the arrangement according to Alekseev et al. (i.e. milk bottle near the breast) corresponds to the commonly used arrangement, and since no hint can be found in either of the two references cited that the milk bottle can be placed farther away from the mother's breast, the combination of Alekseev et al. with Jaquith does not logically produce the claimed invention.

The inventive system has the additional advantage that a normal breast shield can be used instead of the rather complicated system of Alekseev et al. The mother therefore does not have to handle an inconvenient or specialized tool. The risk is minimized that the mother will feel uncomfortable, and that the detected surge data does not accurately correspond to a milk surge under normal circumstances.

Claims 3, 4, 5 and 8 are not rendered obvious. Reconsideration is respectfully requested.

Respectfully submitted,



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